510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K060310

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Heather Tanner
Reliant Technologies, Inc.
464 Ellis St.
Mountain View, CA 94043
650 641-5861
650 473-0537 fax
htanner@reliant-tech.com

NAME OF DEVICE

Trade Name:	Fraxel II SR Laser System and Accessories
Common Name:	Laser Surgical Instrument
Regulation Number	878.4810
Product code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

LEGALLY MARKETED PREDICATE DEVICES

Name: Fraxel SR Laser System and Accessories
510(k) #: K050841

Name: Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories
510(k) #: K022060

DEVICE DESCRIPTION

The Fraxel II SR Laser System consists of a set of fiber lasers, controlled by an embedded processor, to be used in dermatology. The laser system uses scanning and focusing optics to deliver a pattern of thermal energy to the epidermis and dermis. Device accessories include tip kits and pre-treatment solution.

INDICATION FOR USE STATEMENT

The Fraxel II SR Laser System is intended for use in:

Dermatological procedures requiring the coagulation of soft tissue;

Treatment of periorbital wrinkles;

Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and dyschromia;

Skin resurfacing procedures.

SUBSTANTIAL EQUIVALENCE COMPARISON

Indications for Use

Substantial equivalence for the Fraxel II SR Laser System and Accessories is supported by the predicate devices listed in this submission, which have identical or similar indication statements.

Clinical Performance Data

Clinical analysis was conducted on Non-Significant Risk and IDE Reliant studies to support the clinical performance of the Fraxel SR Laser System. Sufficient safety data has been gathered to determine that the Fraxel II Laser System and Accessories performs as clinically intended and that no new issues of safety and effectiveness are introduced.

Technological Characteristics

Key technological characteristics of the Fraxel II SR Laser System, such as energy type and operating principle, are equivalent to the Fraxel SR Laser System as described in submission K050841, K042319, K040617 and K031795.

CONCLUSION

Based on the design, materials, function, intended use and clinical evaluation, the Fraxel II Laser System and Accessories is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. No changes are being made in the laser wavelength or operating principle. Safety and effectiveness are reasonably assured, justifying 510(k) clearance.

PREDICATE DEVICES

Name: Fraxel SR Laser System
510(k) #: K053047

Name: Reliant Laser System II
510(k) #: K040617

Name: Reliant Laser System
510(k) #: K031795

Name: Lumenis UltraPulse Encore
Carbon Dioxide Surgical Laser
and Delivery Device Accessories
510(k) #: K022060

DEVICE DESCRIPTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Reliant Technologies, Incorporated
c/o Ms. Heather Tanner
464 Ellis Street
Mountain View, California 94043

Re: K060310
Trade/Device Name: Fraxell II SR Laser System and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 2, 2006
Received: February 7, 2006

Dear Ms. Tanner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

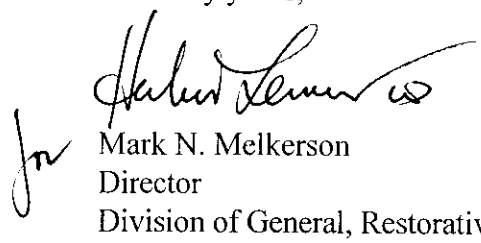
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 060310

Device Name: Fraxel II SR Laser System and accessories
Indications For Use:

Dermatological procedures requiring the coagulation of soft tissue;

Treatment of periorbital wrinkles;

Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), melasma and dyschromia;

Skin resurfacing procedures."

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060310